

## REMARKS

### *Status of the Claims*

Claims 1-3, 8-13, 19, 20, 29-31 and 39 are pending in the application.

Claims 1-3, 8-13, 19, 20, 29-31 and 39 have been rejected.

The Official Action dated January 29, 2008 was made final.

By way of this amendment, new claims 40-48 have been added.

Upon entry of this amendment, claims 1-3, 8-13, 19, 20, 29-31 and 39-48 will be pending.

### *Summary of the Amendment*

The specification has been amended to expressly recite GenBank accession numbers corresponding to protein and/or nucleic acid sequences for human CDX1. These GenBank accession numbers are set forth on page 4 of the priority provisional application. The instant specification as filed states in the first paragraph on page 1 that the parent application, Application Serial No. 09/819,254 filed March 27, 2001, and the priority provisional application, Provisional Serial No. 60/192,229 filed March 27, 2000, are each incorporated herein by reference. Likewise, the parent application, Serial No. 09/819,254 filed March 27, 2001, states in the first paragraph on page 1 that the priority provisional application, Serial No. 60/192,229 filed March 27, 2000, are both incorporated herein by reference. Accordingly, the GenBank accession numbers added herein by amendment have support in the present application, the parent application and the priority provisional application. The amendment does not add new matter.

New claims 40-48 refer to specific embodiments of the invention. No new matter has been added.

*Claim Rejections Under 35 U.S.C. §112, first paragraph*

Claims 1-3, 8-13, 19, 20, 29-31 and 39 stand rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement. The Office asserts that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In Applicants' earlier amendment, the specification was amended to refer to SEQ ID NO:1 as a representative example of the sequence of CDX1. The Official Action dated January 29, 2008 states on page 3 that:

SEQ ID NO:1 disclosed in the instant specification does not match any art-known sequence although the specification reasonably communicates that applicants have not discovered new CDX1 sequence.

This conclusion is based upon search results provided in the Official Action. The search compared SEQ ID NO:1 to sequences in the GenEmbl databases and the results revealed several non-identical sequences for CDX1, including GenBank Accession No. U51095 and GenBank Accession No. U15212, which are disclosed in the priority provisional application and were incorporated into the instant specification by reference. The closest sequence found in the search contained 5 mismatches relative to the CDX1 sequence set forth in SEQ ID NO:1. While the Office has cited a sequence that differs from SEQ ID NO:1, these additional sequences demonstrate that the difference between SEQ ID NO:1 and the CDX1 sequence cited by the Office does not support a conclusion that one skilled in the art would not accept Applicants' SEQ ID NO:1 as a CDX1 sequence.

Applicants filed a response pursuant to 37 CFR 1.116 on March 31, 2008. In it, Applicants provided copies of two exhibits which were results from a Genbank search using the terms "human CDX1". One exhibit, Exhibit A (a copy of which is attached hereto) - GenBank Accession No. U51095 dated November 28, 2000, sets forth a full length CDX1 sequence which contains the same sequence mismatches to the CDX1 sequence cited by the

Office as the sequences in SEQ ID NO:1. The Advisory Action dated April 21, 2008 sent in response to Applicants' request for reconsideration filed March 31, 2008 states as a reason for not placing the application in condition for allowance that:

SEQ ID NO:1 is new matter. Applicant argues that two attached GenBank accession numbers (i.e. U51095 and AF239666) have the same mismatches. This argument has been fully considered but found unpersuasive because both GenBank accession numbers have PRI 28-NOV-2000 and 30-MAR-2000, respectfully, which are after the effective filing date of the instant application (03/27/2000 to the provisional application 60/192,229). Therefore these provided sequences must be updated sequences after the effective filing date of the instant application. Applicants were not in possession of the sequences which has priority date after the effective filing date of the instant application.

The position of the Office, as forth in the Advisory Action dated April 21, 2008 as well as the Office Action dated January 29, 2008, is incorrect on several grounds.

First, the assertion that SEQ ID NO:1 is new matter is improperly raised for the first time in the Advisory Action. The proper time to have raised the issue would have been in the Official Action dated January 29, 2008 and some reasoning to reflect the basis for the assertion should have been included.

Second, SEQ ID NO:1 is in fact not new matter. The specification as filed discloses SEQ ID NO:1. There is no factual reason or legal basis to support a conclusion that SEQ ID NO:1 is new matter. The rejection based upon an assertion that SEQ ID NO:1 is new matter is improper.

Finally, the sequence provided in SEQ ID NO:1 would be accepted by those skilled in the art as a CDX1 sequence. Applicants' assertion on in the specification as filed that SEQ

ID NO:1 corresponds to a CDX1 sequence is clear and unambiguous. The Official Action dated January 29, 2008 states on page 3 that:

SEQ ID NO:1 disclosed in the instant specification does not match any art-known sequence although the specification reasonably communicates that applicants have not discovered new CDX-1 sequence.

The specification is silent as to whether or not all CDX1 sequences are identical. Moreover, at the time the application was filed, the sequence set forth in GenBank accession number U51095 was publically available on GenBank. As pointed out by the Office, the sequence record in GenBank indicates that the sequence record for GenBank accession number U51095 was updated on November 28, 2000. A review of the GenBank records for this sequence shows that the sequence was currently displayed in its current form prior to the November 28, 2000 update. The Revision History for GenBank accession number U51095, which may be accessed through the "Reports" link found on the webpage of the GenBank accession number U51095 record, shows that an earlier version of GenBank accession number U51095 was posted on January 14, 1997. A review of the sequence in the earlier posting to the sequence following the November 28, 2000 update reveals the sequences to be the same.

Applicants attach hereto Exhibits A2 and A3 as evidence that the sequence set forth in Exhibit A was publically available prior to the priority filing date. Exhibit A2 which is a copy of the webpage of the Revision History for GenBank accession number U51095, and Exhibit A3 which is a copy of the webpage of the record for U51095 dated January 14, 1997. In addition, for convenience, attached hereto a duplicate copy of Exhibit A which is submitted with the response filed March 31, 2008. The duplicate copy of Exhibit A has the "Reports" link circled. As noted above, a comparison of the sequence in Exhibit A with the sequence in Exhibit A3 ,shows that each is identical to the other.

GenBank accession number U51095 is one of the GenBank accession numbers corresponding to CDX1 sequences expressly set forth on page 4 of the priority provisional

application. By way of this amendment, the specification has been amended to expressly refer to those GenBank accession numbers which were incorporated into the disclosure by reference. The specification, by its incorporation by reference of the priority provisional application and expressly as amended, lists multiple examples of CDX1 sequences.

At the time the application was filed, Applicants were in possession of the claimed invention. At the time the application was filed, Applicants were in possession of methods of screening individuals for the presence of evidence of expression of CDX1. One skilled in the art would recognize that Applicants were in possession of the claimed invention.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

### ***Conclusion***

Claims 1-3, 8-13, 19, 20, 29-31 and 39-48 are in condition for allowance. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned attorney at 610.640.7855 to clarify any unresolved issues raised by this response.

The Commissioner is hereby authorized to charge any debit or credit any overpayment to Deposit Account No. 50-0436.

Respectfully submitted,

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**Attachments:**

Exhibit A (previously submitted): GenBank accession number U51095  
Exhibit A2 Revision History for GenBank accession number U51095  
Exhibit A3 GenBank accession number U51095 record dated January 14, 1997